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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,084	12/15/2003	Joseph C. Walsh	2003P88073 US	3273
28524 SIEMENS COI	7590 12/18/2006 R POR A TION	EXAMINER		
INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830			KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MO	NTHS	12/18/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
Office Action Summany	10/736,084	WALSH ET AL.				
Office Action Summary	Examiner	Art Unit				
	Ganapathy Krishnan	1623				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on 15 Se	Responsive to communication(s) filed on 15 September 2006.					
3) Since this application is in condition for allowar						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-32</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-32</u> is/are rejected.	• • • • • • • • • • • • • • • • • • • •					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.	•				
Application Papers						
9) The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	4) Interview Summary ( Paper No(s)/Mail Dat 5) Notice of Informal Pa	e				
Paper No(s)/Mail Date 6)						

#### **DETAILED ACTION**

The amendment filed 9/15/2006 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

- 1. Claims 33-34 have been canceled.
- 2. Claims 1, 4, 10-12, 21 and 30 have been amended.
- 3. Remarks drawn to claim objections and rejections under 35 USC 112, first and second paragraphs and 103.

Claims 1-32 are pending in the case.

#### Title

The objection to the title has been overcome by providing a new title that is indicative of the invention to which the pending claims are directed.

## Claim Objections

The objections to claims 1, 12, 21, 29 and 30 have been overcome by providing structures that are clear.

## Claim Rejections - 35 USC § 112

The rejection of claims 10-11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the nucleoside as instantly claimed wherein the base is thymidine and uridine, does not reasonably provide enablement for making the nucleoside wherein the base is other than thymidine or uridine, has been overcome by

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amendments. The rejection of claims 30-32 advanced in the previous office action is being withdrawn since the claims as originally presented recite thymidine structures, for which enablement is present in the specification.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendments to claims 1, 2, 10, 12 and 21.

#### Claim Rejections - 35 USC § 103

The rejection of claims 21-32 under 35 U.S.C. 103(a) as being unpatentable over Acevedo et al (US 6,060,592) has been overcome in view of applicants arguments.

The following new art rejection is made of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al (The Journal of Organic Chemistry, 1968, 33(4), 1592-99) in combination with Miller et al (J. Org. Chem. 1963, 28, 936-41).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Fox et al teach the preparation of compound 8, a thymidine derivative (page 1593, Figure 2). This compound is structurally the same as the compounds in instant claims 21 and 30 except that the 5' hydroxyl group is protected in the instant compound. The compound of Fox has a leaving group (mesylate) as instantly claimed. The compound of Fox serves as an intermediate for making several derivatives of compound 6 that are biologically active (page 1592, right column, lines 1-5).

According to Miller et al, thymidine derivatives II (page 936, Figure 1) are also useful intermediates I the syntheses of nucleosides of potential value as antitumor agents (page 936, left column, first paragraph). Compound II of Miller is structurally very close to that of the compound claimed in instant claim 29 except that the carbonyl group in the base is not present as an enolate. But such an enolate structure is an important intermediate as taught by Fox (above).

Fox teaches the conversion of the anhydro intermediate 4 to the derivative 5, which is the same as the compound obtained in step (c) of instant claim 1. A derivative that structurally

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similar to the compound in step (a) of claim 1 (the protected derivative) is taught by Miller (structure III of Miller in Figure 1). Even though the structure of the anhydro derivatives are slightly different in both Fox and Miller one of ordinary skill in the art will recognize that the sequence of steps can be applied to make the compound in instant claim 1 via the steps as instantly claimed with slight modifications. Such a modification based on the prior art is well within the purview of one of ordinary skill in the art.

Based on the teachings of the prior art, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make compounds as claimed in instant claims 21-30 via the process as claimed in instant claims 1-20 since structurally very close compounds as instantly claimed and steps for the same are seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to make compounds as instantly claimed via the process as instantly claimed and taught by the prior art, since they serve as intermediates for the syntheses of several other derivatives having biological activity including antitumor activity as taught by Fox and Miller. It is well within the purview of one of ordinary skill in the art to substitute other protecting groups and leaving groups as instantly claimed since all of these groups are well known in the art for use in such synthetic methods as instantly claimed and would extend the scope of the method.

### Conclusion

Claims 1-32 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

Shaojia Jiang

Supervisory Patent Examiner

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